UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA EX REL. YOASH GOHIL, Plaintiff/Relator, v. SANOFI U.S. SERVICES, INC. et al., Defendants.	:	No. 02-CV-2964 Hon. Anita B. Brody

MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

This case is about the revolutionary chemotherapy drug Taxotere, and its manufacturer's lawful efforts to ensure Taxotere would save as many lives as possible. Since Taxotere first received Food and Drug Administration ("FDA") approval in 1996, it has saved or prolonged countless lives worldwide. Renowned oncologists have viewed Taxotere as a miracle drug, and its versatility has led to the successful treatment of various cancer disease states, even before the FDA approved some uses. Oncologists, seeking the most effective treatment for the second leading of cause of death in the United States, exercised their independent clinical judgment to prescribe Taxotere "off label," a common and well-accepted practice in oncology.

Aware of Taxotere's life-saving potential, Rhône-Poulenc Rorer Pharmaceuticals, Inc. ("RPR"),[1] a predecessor to Defendants Sanofi U.S. Services, Inc., Aventis, Inc., and Aventisub, LLC (collectively, "Defendants" or "Aventis"), directed its sales staff to market Taxotere lawfully throughout the oncology community, worked with oncologists to educate their peers about Taxotere's clinical benefits, and funded clinical trials to explore its full potential. At the same time, Aventis implemented a robust compliance program, enacted comprehensive compliance policies, and administered routine trainings to ensure that sales representatives only promoted Taxotere for FDA-approved uses and to guarantee that its fee-for-service relationships with prescribing oncologists were lawful. While the laws and standards governing drug marketing and promotion developed significantly between the relevant period of 1996 to 2004—and continued to evolve thereafter—Aventis anticipated and adapted to each development, took its obligations seriously, and strove at all times to comply with applicable laws and guidance.

[1] In 1999, RPR merged with Hoechst Marion Roussel ("HMR") to form Aventis, which merged in 2005 with Sanofi Syntholab, Inc. Today, the company is known as Sanofi. Third Am. Compl., ECF No. 134, ¶ 5.

Despite Taxotere's therapeutic benefits and Aventis's rigorous compliance efforts, Relator Yoash Gohil ("Relator" or "Gohil") has spent nearly twenty years arguing that Aventis's alleged remuneration to physicians and improper promotional practices—rather than scientific evidence and sound clinical decision-making—caused oncologists to prescribe Taxotere off-label. Motivated solely by personal profit, Gohil misapprehends a regulatory regime that expressly permits off-label prescriptions and their reimbursement, second-guesses physicians' clinical judgment, and seeks to foist present day legal and industry standards backwards in time. Yet, after decades of litigation, Gohil can point to no evidence to disprove the simple and dispositive fact that oncologists prescribed Taxotere for one reason: it saved or extended the lives of their very sick patients. Gohil has proffered insufficient evidence to raise a triable issue of fact supporting his claims that Aventis unlawfully caused the submission of false claims to the Government. Accordingly, Aventis' motion for summary judgment should be granted and judgment should be entered in its favor on all claims in the Third Amended Complaint ("TAC").

THE UNDISPUTED MATERIAL FACTS WARRANT SUMMARY JUDGMENT

I. Background and Procedural History.

Gohil filed his original complaint under seal in 2002. SUMF ¶ 1, ECF No. 1. Since then, his shifting theories of liability and the Court's repeated dismissals have led him to file three amended complaints. SUMF ¶ 2, Ex. 1, First Am. Compl.;[2] ECF Nos. 45 & 134. The four-count TAC is the operative pleading and, in sum, alleges that from 1996 through 2004 (the "Relevant Period") Aventis violated the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq.*, by unlawfully marketing and promoting Taxotere for off-label uses and paying kickbacks to

[2] The FAC was filed under seal and upon inquiring with the Court about its docket number for citation, Aventis was informed that the docket number itself is under seal.

physicians, both of which allegedly led physicians to submit false claims for reimbursement to federal insurers.[3] SUMF ¶¶ 3–4.

When he filed the initial complaint, Gohil furnished extensive information to the United States Attorney's Office for the Eastern District of Pennsylvania ("EDPA") to encourage the Government to intervene in his case, including more than 36,000 pages of documents as well as his counsel's detailed explanations as to why this "evidence" established violations of the FCA and AKS. *See generally* SUMF ¶ 5, Ex. 2, Compilation of Relator's Disclosures to Gov't. From 2002 through 2006, these detailed explanations were made by email and in approximately thirty letters with the EDPA. *See generally* SUMF ¶ 6, *id*. Gohil also communicated with the Department of Health and Human Services ("DHHS") about Aventis's alleged misconduct. *See, e.g.*, SUMF ¶ 7, *id.* at GOH/COD000400. In turn, the Government investigated Gohil's ever-shifting allegations for four years before declining to intervene in Gohil's initial complaint, and then again in his 2007 and 2015 amended complaints. *See, e.g.*, SUMF ¶ 8, ECF No. 24.

II. Taxotere Revolutionized the Field of Oncology.

Clinical research studies and oncologist testimony confirm that Taxotere revolutionized oncology.[4] Taxotere, a chemotherapy drug, first received FDA approval in 1996 as second-line therapy for locally advanced metastatic breast cancer. SUMF ¶ 10, Ex. 3A, New Drug Application Approval Letter from FDA (May 14, 1996). Its clinical benefits led to its later FDA

[3] While there is no private cause of action for violating the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b, AKS violations can serve as a predicate for a violation of the FCA.

[4] *See generally* SUMF ¶ 9, Ex. 4, Arnold Decl.; Ex. 5, Austin Decl.; Ex. 6, Barker Decl.; Ex. 7, Dugan Decl.; Ex. 8, Eisenberger Decl.; Ex. 9, George Decl.; Ex. 10, Scholz Decl.; Ex. 11, Vogelzang Decl.

approval for four new indications between 1996 and 2004,[5] and various medical compendia listed Taxotere uses supported by clinical data and therefore appropriate for "off-label" use.[6]

Beyond the FDA-approved and compendia-listed uses, a veritable library of medical evidence demonstrated Taxotere's off-label efficacy during the Relevant Period. Clinical study after clinical study confirmed Taxotere's versatility in effectively treating a range of cancers.[7] For example, while the FDA did not approve Taxotere for metastatic prostate cancer until 2004, clinical research showed the life-saving benefits of Taxotere for prostate cancer as early as 1999. SUMF ¶ 15, Ex. 12, Daniel Petrylak, *Chemotherapy for Advanced Hormone Refractory Prostate Cancer*, 54 UROLOGY 30, 34 (1999). This research revealed Taxotere as the first chemotherapeutic treatment that offered life-extending—rather than purely palliative—benefits to prostate cancer patients. SUMF ¶ 16, Ex. 13, J. Unger et al., *The Diffusion of Docetaxel in Patients With Metastatic Prostate Cancer*, 107 J. NAT'L CANCER INST. 1 (2015). Because of its

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[5] Those indications were second-line treatment for locally advanced or metastatic non-small cell lung cancer ("NSCLC") (Dec.1999), first-line treatment for the same (Nov. 2002); metastatic prostate cancer (May 2004); and operable node-positive breast cancer (Aug. 2004). *See* SUMF ¶¶ 11, 12, Ex. 14, Cockburn Report at 6 (Table 1); *see also* Ex. 3, Demonstrative Exhibit Detailing Taxotere's FDA-Approved Indications.

[6] Medical compendia summarize drug information compiled by medical experts who review clinical data and determine appropriate off-label uses for drugs. For example, then-leading compendium, U.S. Pharmacopeia Drug Index ("USP-DI") recommended Taxotere for: first-line treatment for locally advanced or metastatic breast cancer, (USP-DI 1998); second-line therapy for small cell lung cancer (USP-DI 1998); second-line therapy for ovarian carcinoma (USP-DI 1998); advanced, recurrent, or metastatic head and neck carcinoma (USP-DI 2001); urotherial carcinoma (USP-DI 2001); esophageal cancer (USP-DI 2002); and advanced or metastatic gastroesophageal junction carcinomas (USP-DI 2002). SUMF ¶¶ 11, 13, Ex. 15D, USP-DI, *Docextaxel* (1998); Ex. 15J, *Docextaxel* (2001); Ex. 15L, *Docextaxel* (2002); *see also* Ex. 14, Cockburn Report at 6 (Table1).

[7] *See, e.g.*, SUMF ¶ 14, Ex. 16, Frank Fossella et al., *Randomized, Multinational, Phase III Study of Docetaxel Plus Platinum Combinations Versus Vinorelbine Plus Cisplatin for Advanced Non-Small-Cell Lung Cancer: The TAX 326 Study Group*, 21 J. CLINICAL ONCOLOGY, 1, 7 (Aug. 15, 2003) (TAX 326) (concluding a Taxotere combination is "an effective treatment option with a favorable therapeutic index for use in first-line therapy of patients with advanced or metastatic NSCLC"); Ex. 17, P. A. Vasey et al., *Docetaxel-carboplatin as first line chemotherapy for epithelial ovarian cancer*, 84 BRITISH J. CANCER 170, 176 (2001) (concluding that a Taxotere combination can be "safely and with significant efficacy" used as "first line chemotherapy for patients with advanced epithelial ovarian cancer"); Ex. 18, Ian F. Tannock et al., *Docetaxel plus Prednisone or Mitoxantrone plus Prednisone for Advanced Prostate Cancer*, 351 N. ENG. J. MED. 1502, 1511 (Oct. 7, 2004) (concluding a docetaxel [Taxotere] combination "is the preferred option for most patients with hormone-refractory prostate cancer."). *See also* Ex. 14, Cockburn Report at 17 (noting that fifty-one Phase II and III clinical trials for Taxotere were completed by the end of 2004).

clinical superiority to other FDA-approved drugs, Taxotere became the standard of care for prostate cancer before its 2004 approval. SUMF ¶ 17, Ex. 11, Vogelzang Decl. ¶ 8, 10.

During the Relevant Period, oncologists, who were trained to make complex treatment decisions based on emerging clinical data, patient profile, and drug toxicity, among other factors,[8] regularly exercised their clinical judgment to prescribe Taxotere both on- and off-label. SUMF ¶ 18, Ex. 19, Goldberg Report 8–9. According to these oncologists, Taxotere offered certain patients hope for survival and improved quality of life at a time when few other treatment options existed. SUMF ¶ 22, Ex. 10, Scholz Decl. ¶ 8; Ex. 11, Vogelzang Decl. ¶¶ 8–11. For example, approximately nineteen years ago, oncologist Dr. Mariette Austin treated "Patient X" for metastatic ovarian cancer. SUMF ¶ 23, Ex. 5, Austin Decl. ¶ 12. After Patient X nearly died from an anaphylactic reaction to an on-label chemotherapy drug, Dr. Austin, left with few alternatives, decided based on her medical judgment to treat Patient X with Taxotere, which was unapproved for metastatic ovarian cancer. SUMF ¶ 24, *id.* ¶ 12. This allowed Dr. Austin to treat her patient without significant side effects. SUMF ¶ 25, *id.* ¶ 12. As Dr. Austin summarized, in oncology, "there is a story behind every off-label use." SUMF ¶ 26, *id.* ¶ 14.

III. Medically Reasonable and Necessary Uses of Taxotere Are Reimbursable under Federal Law.

For patients who relied on off-label treatment during the Relevant Period, as today, federal law required federal insurers to reimburse the overwhelming majority of off-label

[8] Oncologists rely on various factors to determine whether to prescribe a drug off-label, including information provided by pharmaceutical companies; clinical trials, scientific literature, and compendia; treatment guidelines published by private organizations; physician experience; and individual patient characteristics. SUMF ¶ 19, Ex.14, Cockburn Report § III. Chief among these are physicians' reliance on their own experience, medical literature, and treatment guidelines. Research has shown that physicians who prescribed drugs for one patient are more likely to use the drug off-label again. SUMF ¶ 20, *Id.* ¶ 52. A thorough review of Taxotere prescriptions confirms this, showing that 10% of oncologists who prescribed Taxotere during the Relevant Period accounted for more than 90% of all Taxotere prescriptions, suggesting personal experience influenced prescription decisions. SUMF ¶ 21, *Id.* ¶ 54.

prescriptions for cancer drugs like Taxotere.[9] Federal insurers must reimburse off-label chemotherapy where the off-label use is listed in a statutorily recognized medical compendium and supported by publications in enumerated medical journals. SUMF ¶ 28, *id.* Likewise, federal insurers may reimburse off-label chemotherapy so long as the use is "reasonable and necessary."[10] To determine whether a particular use of a drug is "reasonable and necessary," federal insurers examine whether the drug is FDA approved for *any* use, and consider the opinions of local medical societies, a consensus of expert medical opinion, consultations with medical staff, clinical guidelines, and any other relevant resources. SUMF ¶ 33, Ex. 20, DHHS, *MACs Continue to Use Different Methods to Determine Drug Coverage* (2016), at 3. Ultimately, federal insurers reimburse when the use is consistent with these factors—thus, "off-label use … is not the same as medically unnecessary use."[11] While prescribing drugs off-label is generally "commonplace," *Ironworkers Local Union 68 v. AstraZeneca Pharm., LP*, 634 F.3d 1352, 1356 (11th Cir. 2011), oncologists in particular routinely treat cancer patients with drugs prescribed

9 Congress authorized reimbursement for the off-label use of chemotherapy drugs like Taxotere in the Omnibus Budget Reconciliation Act of 1993 ("OBRA93"). SUMF ¶ 27, OBRA93, Pub. L. 103-66 § 13553(b)(2)(A)(1), codified at 42 U.S.C. § 1395x(t)(2)(A) (effective Jan. 1, 1994); 42 U.S.C. §§ 1396r–8(a)(1), (g)(1)(B)(i), (k)(6). OBRA93 expanded Medicare Part B coverage of off-label chemotherapy drugs, such as Taxotere, by amending the drug definition to include chemotherapeutic regimen used for a "medically accepted indication." SUMF ¶ 30, *Id.* In turn, OBRA93 modified Section 1927 of the Social Security Act, which required that Medicaid provide coverage for "medically accepted indications." 42 U.S.C. §§ 1396r–8(a)(1), (g)(1)(B)(i), (k)(6). *See also* SUMF ¶ 31, Ex. 21, Romano Report ¶ 13–15.

10 SUMF ¶ 32, Ex. 22, CMS Manual § 2049.4 (2002; reprinting 1993 Manual); Ex. 23, CMS Manual (2001, reprinting 1996 manual); Ex. 24, CMS Manual § 2049.4 (2003); Ex. 25, CMS Manual § 2049.4 (2004). *See also* SUMF ¶ 32, Ex. 21, Romano Report ¶ 13–17.

11 SUMF ¶ 34, *U.S. ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 751 (S.D. Tex. 2010) (granting summary judgment to defendant in FCA matter); *U.S. ex rel. Sullivan v. Atrium Med. Corp.*, No. CV SA-13-CA-244-OLG, 2015 WL 13799885, at *13 (W.D. Tex. Nov. 20, 2015) (dismissing FCA allegations); *see also U.S. ex rel. Polansky v. Pfizer*, No. 04-cv-0704, 2009 WL 1456582, at *6 (E.D.N.Y. May 22, 2009) (FDA "acknowledged that 'accepted medical practice often includes drug use that is not reflected in approved drug labeling'").

off-label. SUMF ¶ 35, Ex. 14, Cockburn Report ¶¶ 18–19.[12] A critical reason why oncologists prescribe cancer drugs off-label is that medical research and pharmacology often outpace the long and onerous FDA approval process.[13] SUMF ¶ 37, Ex. 14, Cockburn Report ¶¶ 21–22. As Aventis's oncology expert explained, "[d]elaying effective off-label treatment in [some] cancer[s] … would deny patients life-saving and life-extending benefits." SUMF ¶ 40, Ex. 19, Goldberg Report at 13. Further, the FDA itself recognized that oncologists are uniquely situated to prescribe drugs consistent with their medical judgment regardless of the drug's approved indication or labeling. SUMF ¶ 41, Ex. 27, Bradshaw Report ¶¶ 67–73. Because standards of care can also outpace FDA review, SUMF ¶ 42, Ex. 27, Bradshaw Report ¶ 72, "oncologist[s] will not, and should not, wait for a new FDA label before incorporating a new standard of care into their practice." SUMF ¶ 42, Ex. 19, Goldberg Report. at 12. Off-label prescriptions for cancer drugs like Taxotere are part-and-parcel of legal, successful, and responsible oncology practices. SUMF ¶ 43, *id*.

IV. Aventis Promoted Taxotere On-Label, and Administered Its Programs in Good Faith, without the Benefit of Official Guidance.

Aventis sought at all times to comply with FDA regulations prohibiting off-label promotion, and to ensure that its use of promotional and educational programs complied with the

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[12] According to one seminal study, "56 percent of the cancer patients were given at least one drug off-label, and about a third of them received at least one drug for a treatment not cited in the compendia." SUMF ¶ 36, Ex. 26, U.S. Gen. Accounting Office, *Off Label Drugs: Reimbursement Policies Constrain Physicians in Their Choice of Cancer Therapies*, GAO/PEMD–91–14, at 3, 21 (Sept. 1991). Relatedly, about 50% of all single-dose cancer drugs and about 80% of combination cancer therapies are prescribed off-label. SUMF ¶ 36, Ex. 14, Cockburn Report ¶ 19.

[13] Off-label use often benefits the medical community because it allows physicians to provide therapeutic benefits and meet patients' medical needs without waiting for FDA approval. SUMF ¶ 38, Ex.14, Cockburn Report ¶ 21; Ex. 19, Goldberg Report at 12. Furthermore, sick and dying patients often do not have time to wait for such approvals. *See* SUMF ¶ 39, Ex. 4, Arnold Decl. ¶ 10; Ex.5, Austin Decl. ¶ 7; Ex. 6, Barker Decl. ¶ 7; Ex. 7, Dugan Decl. ¶ 10; Ex. 9, George Decl. ¶ 9; Ex. 10, Scholz Decl. ¶ 9; Ex. 11, Vogelzang Decl. ¶ 11.

AKS. These compliance efforts refute Gohil's attempt to recast the conduct of a few rogue employees as a sweeping campaign to induce medically unnecessary prescriptions.

A. From 1996 to 2003, Pharmaceutical Industry Lacked Comprehensive Guidance on Propriety of Relationships with Physicians.

Aventis engaged in meaningful relationships with oncologists by (1) promoting Taxotere on-label and developing oncologists' understanding of the drug's approved uses, and (2) researching the breadth of Taxotere's clinical potential. *Infra* Facts § V. Until 2002, Aventis and its pharmaceutical industry peers largely engaged with physicians in a regulatory vacuum given that neither the Government nor the industry had released comprehensive guidance for the application of otherwise broad and non-specific statutes governing promotional or educational activities. SUMF ¶ 45, Ex. 28, Zoffer Report ¶¶ 15, 43; Ex. 29, Baylor-Henry Report ¶¶ 67–75 (noting absence of guidance pre-2002). For example, due to the broad, sweeping scope of the AKS's literal language and the lack of guidance, Aventis and its peers were left to make reasonable, good-faith judgments about how to implement its programs lawfully. *See* SUMF ¶ 46, *id.* Despite the lack of guidance, Aventis lawfully implemented policies and procedures in a good-faith attempt to govern its promotional and educational programs. *Infra* Facts § IV(B).

This all changed in 2002 and 2003. First, in 2002, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), a pharmaceutical industry group of which Aventis was a member, adopted its hallmark marketing code to govern relationships between physicians and manufacturers. SUMF ¶ 48, Ex. 30B, PhRMA, *PhRMA Code on Interactions with Healthcare Professionals*, July 1, 2002 ("2002 PhRMA Code"); Ex. 29, Baylor-Henry Report ¶¶ 73–75, 77–78. Then, in 2003, eight years into the nine-year Relevant Period and for the first time in the pharmaceutical industry's history, the Government articulated a formal position on physician-manufacturer interactions. SUMF ¶ 49, Ex. 30C, OIG Compliance Program Guidance for

Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003) ("2003 OIG Guidance"). These statements, for the first time, suggested boundaries and guidelines for physician-manufacturer relationships "previously left to the discretion of physicians and the pharmaceutical industry." SUMF ¶ 50, Ex. 29, Baylor-Henry Report ¶ 68.

The particularly influential 2003 OIG Guidance recommended basic elements of an effective compliance program, and identified the AKS as a "key area of potential risk." SUMF ¶ 51, Ex. 30C, 2003 OIG Guidance at 23,734–35. Given possible AKS implications, the guidance included recommendations for research funding;[14] consulting, advisory, and preceptorship services;[15] and educational and research funding. SUMF ¶ 52, *id.* Collectively, the 2002 PhRMA Code and 2003 OIG Guidance ushered in a new era of more restricted physician-pharmaceutical interactions, and imposed standards on the pharmaceutical industry that did not previously exist.[16] SUMF ¶ 58, *id.*

B. Aventis Implemented Policies to Comply with the Law and Official Guidance.

Aventis had legitimate and legal commercial interests in understanding and developing Taxotere's full clinical value for both on- and off-label uses. *See* SUMF ¶ 60, Ex. 19, Ex. 31,

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[14] Research funding "provides valuable scientific and clinical information, improves clinical care, leads to promising new treatments, promotes better delivery of health care, or otherwise benefits patients." SUMF ¶ 53, *Id.* at 23,736. "Payments for research services should be fair market value for legitimate, reasonable, and necessary services." SUMF ¶ 54, *Id.* at 23,735. The guidance also warned against linking research funding to the purchase of the company's product. SUMF ¶ 55, *Id.*

[15] SUMF ¶ 56, *Id.* at 23,738 (approving consulting and advisory relationships where physicians are paid fair market value for bona fide consulting or advisory services, and where physicians are not carrying out a marketing or sales activities). The guidance recommends that: (1) speaker arrangements be set out in writing; (2) there be a legitimate need for the services; (3) the services actually be provided; (4) speakers be compensated at fair market value; and (5) points (2) through (4) be documented in writing. SUMF ¶ 57, *Id.*

[16] Although this Guidance was not law and did not have the effect of law, it did provide recommended boundaries to provide definition to the broad and boundless enforcement laws that governed promotional practice and financial relationships or transactions with physicians and healthcare institutions. *See, e.g.*, SUMF ¶ 59, Dep't of Justice, *Justice Manual* § 1.20-100 (2018), https://www.justice.gov/jm/justice-manual. (guidance documents cannot by themselves create binding requirements that do not already exist by statute or regulation).

Naigamwalla Report ¶ 116. As discussed above, oncologists widely used Taxotere, like many cancer drugs, off-label. *See* SUMF ¶ 61, Ex. 19, Goldberg Report 8–9. The clinical results of this widespread off-label use helped Aventis learn the full range of Taxotere's therapeutic benefits, determine which indications warranted the expenditure of additional resources for further research and clinical studies, and to develop the clinical data necessary to expand FDA indications. SUMF ¶ 62, Ex. 31, Naigamwalla Report, ¶¶ 76–79, 116. Likewise, research and training for off-label Taxotere uses laid the groundwork for post-FDA-approval marketing strategies. SUMF ¶ 63, Ex. 31, Naigamwalla Report ¶¶ 87–90, 99.

To further these interests and facilitate scientific discourse, Aventis, like its industry counterparts, organized lawful fee-for-service promotional and educational programs, discussed below. SUMF ¶ 64, Ex. 27, Bradshaw Report ¶ 98. These collaborative programs facilitated "the exchange of truthful, non-misleading scientific information" necessary to develop scientific data and advance medicine. SUMF ¶ 64, *id*. According to the former FDA Chief Counsel, these "interactions ... were consistent with industry practice" during the Relevant Period. SUMF ¶ 65, Ex. 27, Bradshaw Report. ¶ 119. Indeed, as early as 1996, Aventis implemented formal written policies to ensure its promotional and educational programs operated in accord with FDA restrictions regarding drug promotion and the AKS. *See generally* SUMF ¶ 66, Ex. 30A, 1996 Policies for Sales Representative Conduct, at SAVGOH-04100000754–837; Ex. 30D, 2003 Policy & Procedure Manual, at SAVGOH-02800174670; Ex. 32, Hogan (Marketing Manager) Dep. 45:15–46:1. These policies limited promotion to physicians likely to use the product on-label, and dissemination of promotional materials to on-label materials approved by Aventis's

promotional review committee.[17] *See generally* SUMF ¶ 67, *id.*[18] Aventis's AKS policies were designed to ensure its physician partnerships served only educational and scientific ends, and were never conditioned on Taxotere prescriptions. *See* SUMF ¶ 73, Ex. 30A, 1996 Policies for Sales Representative Conduct, at SAVGOH-04100000754–837. And while Aventis's pre-2002 policies largely anticipated the 2002 PhRMA Code and 2003 OIG Guidance, Aventis made minor contemporaneous updates to its policies to ensure they were consistent with new guidelines.[19] *See* SUMF ¶ 74, Ex. 33, 1998 Correspondence re Policy Modifications, SAVGOH-04100000714; Ex. 34, 2004 Email re preceptorship policy, at SAVGOH-20700012818; Ex. 35, Corrigan 2019 Dep. 139–40.

Aventis required directors and field personnel to complete trainings on and certify review of these policies. *See, e.g.*, SUMF ¶ 76, Ex. 30A, 1996 Policies for Sales Representative Conduct, at SAVGOH-04100000784.[20] Because compliance efforts can never prevent all wrongdoing, Aventis investigated potential policy violations and punished rogue employees for

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[17] "The Promotional Review Committee … is made up of representatives from Medical Affairs, Regulatory Affairs, Legal, Marketing and Editorial Services." SUMF ¶ 68, Ex. 30A, 1996 Policies for Sales Representative Conduct, at SAVGOH-04100000756.

[18] Contrary to Relator's assertion that Untitled and Warning letters from the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") pertaining to Taxotere promotional materials show evidence of off-label promotion, these letters reflect no unlawful conduct, and if anything, DDMAC's refusal to bring an enforcement action confirms the opposite. SUMF ¶ 69, Ex. 27, Bradshaw Report ¶¶ 101, 151 (former Chief Counsel of the FDA stated that these particular letters were "unremarkable"). By definition, "Untitled Letters" are entirely without regulatory significance. SUMF ¶ 70, *Id.* ¶ 64. And, as former Director of DDMAC stated, "Warning Letters" are "informal and advisory" and do not warrant enforcement action. SUMF ¶ 71, Ex. 29, Baylor-Henry Report ¶ 26. DDMAC issued hundreds of these letters annually throughout the Relevant Period following a "highly subjective" review process that provides no evidence that "FDA's subjective view is correct." SUMF ¶ 72, Ex. 29, Baylor-Henry Report ¶ 61; Ex. 27, Bradshaw Report ¶ 103.

[19] Aventis updated managers and sales personnel when it enacted changes to ensure universal awareness and compliance. *See* SUMF ¶ 75, Ex. 33, 1998 Correspondence re Policy Modifications, SAVGOH-04100000714; Ex. 34, 2004 Email re preceptorship policy, at SAVGOH-20700012818; Ex. 35, Corrigan 2019 Dep. 139–40.

[20] *See also* SUMF ¶ 76, Ex. 36, 2000 Education & Training Binder, at SAVGOH-02800160865; Ex. 37, 2002 Lung Cancer Leader's Guide, at SAVGOH-02800236072; Ex. 38, 1997 Business Ethics Training, at SAVGOH-02800178932; Ex.39 1997 Interoffice Correspondence re Training, at SAVGOH-04100022343.

actual violations.[21] Moreover, Aventis conditioned compensation for sales staff on compliance with these policies.[22]

Deposition testimony confirms these policies were effective, that employees understood Aventis's commitment to compliance, and that, in turn, employees sought to comply with company policy.[23] [24] Likewise, oncologists who interacted with Aventis sales representatives corroborated that Aventis personnel properly promoted Taxotere on-label and that these interactions "did not in any way affect, influence, or induce" Taxotere prescriptions.[25]

V. Aventis Lawfully Engaged Oncologists to Provide Professional Services and Funded Physician-Managed Research Programs.

As noted above, Aventis maintained lawful promotional and educational programs allowing it to work hand-in-hand with the medical community to better understand Taxotere's clinical value, identify and resolve unmet clinical needs, and ultimately save or extend the lives of patients. *See* SUMF ¶ 82, Ex. 31, Naigamwalla Report ¶¶ 6, 25; Ex. 19, Goldberg Report at 9–

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[21] *See* SUMF ¶ 77, Ex. 40, 2000 Promotional Guideline Reviews, at SAVGOH-02800161026–27; Ex. 41, 1996–1998 Employees Terminated or Disciplined for Violation of Policy, at SAVGOH-04100008799.00001–09; Ex. 42, Bruce Ellsworth Final Written Warning, at SAVGOH-02700087336-41; *see also* Ex. 43, Corrigan 2018 Dep. 299:1–7 (recounting having thoroughly documented a report when he observed an incident of a policy violation).

[22] *See, e.g.*, SUMF ¶ 78, Ex. 44, 1999 Compensation Policy, at SAVGOH-02800134852; Ex. 45, 2002 Compensation Policy, at SAVGOH-02800118047; Ex. 46, 2004 Compensation Policy, at SAVGOH-0280062323.

[23] *E.g.*, SUMF ¶ 79, Ex. 47, Fleming (Regional Director of Sales) Dep. 302:17-303:9 (Jan. 29, 2018) ("The message [that Aventis was not going to promote off-label] was conveyed to the sales management team… I made it a point to reinforce multiple times that you need to approach every conversation you have as if there is an attorney in the room making sure that what you're saying is compliant and in line with our approved promotional policy, and equally important, that there is a patient in that room as well. My biggest concern working as a regional director is that we're doing the right thing: we are doing the right thing from a compliance standpoint, we are doing the right thing from the standpoint of the cancer patient, and the right thing from the standpoint of clinicians that we work for.").

[24] Although policies do not create legal obligations, *see* Dep't of Justice, *Justice Manual* § 1.900 (2018), https://www.justice.gov/jm/justice-manual, Aventis management and personnel alike agreed that Aventis and its employees maintained a culture of compliance. SUMF ¶ 80, Ex. 43, Corrigan 2018 Dep. 334:5–20 (showing business plan aligned with policy prohibiting off-label promotion); Ex. 47, Fleming Dep. 292:14–293:12 (stating the only promotional materials and messaging the sales team was instructed to focus on were approved indications).

[25] SUMF ¶ 81, Ex. 4, Arnold Decl. ¶ 11; Ex. 5, Austin Decl. ¶ 8; Ex. 6, Barker Decl. ¶ 8; Ex. 7, Dugan Decl. ¶ 13; Ex. 8, Eisenberger Decl. ¶ 10; Ex. 9, George Decl. ¶ 10; Ex. 10, Scholz Decl. ¶ 10; Ex. 11, Vogelzang Decl. ¶ 12.

10. Notwithstanding these facts, Gohil grounds his claims on a fundamental misunderstanding of the purpose and legality of these programs, alleging they led oncologists to prescribe Taxotere for uses that were not medically necessary and/or induced by alleged kickbacks. TAC, ECF No. 134, ¶ 188. "During much of the Relevant Period, pharmaceutical manufacturers regularly participated in scientific exchange, respond[ed] to unsolicited requests for off-label information, ... sponsored CME events, sponsored healthcare professional speaker programs, [and] engaged healthcare professionals." SUMF ¶ 83, Ex. 27, Bradshaw Report ¶ 119. Here, the evidence reflects Aventis sought to ensure its programs served lawful promotional and educational ends and administered them compliantly. SUMF ¶ 84, Ex. 30, Demonstrative Exhibit Comparing Compliance Policies.[26] Each Aventis promotional and educational program is discussed below.

A. Speaker Programs.

During the Relevant Period, Aventis supported lawful promotional speaker programs consistent with Aventis policy and industry norms. *See* SUMF ¶ 86, Ex. 43, Corrigan 2018 Dep. 75–77.[27] Aventis contracted with physicians to present short, informative lectures to their peers for on-label uses of Taxotere. *See e.g.*, SUMF ¶ 87, Ex. 8, Eisenberger Decl. ¶ 12. These programs allowed physicians to share "experiences in managing difficult cancer conditions," and to "obtain the support and confidence" needed to make difficult clinical decisions. SUMF ¶ 88, Ex. 19, Goldberg Report at 9–10. Aventis limited the content of these presentations to on-label drug uses. SUMF ¶ 89, Ex. 30A, 1996 Policies on Educational Programming, at SAVGOH-

[26] To clarify the substance of these policies pre- and post-2003 Aventis prepared a demonstrative exhibit detailing Aventis's promotional and educational policies from its earliest relevant policy (1996) to its latest relevant policy update (2003), as well as corresponding 2002 PhRMA Code and 2003 OIG Guidance, which reflects that Aventis's early policies largely foreshadowed the guidance that followed years later. SUMF ¶ 85, Ex. 30, Demonstrative Exhibit Comparing Compliance Policies.

[27] Michael Corrigan (National Account Executive, U.S. Market Access Team) served as Aventis's corporate designee under Federal Rule 30(b)(6) on topics including Aventis's promotional and educational policies.

04100000758, 776. Aventis also required physician speakers to present only about such uses. SUMF ¶ 90, Ex. 30A, 1996 Policies for Representative Conduct, Sample Speaker Agreement, SAVGOH-04100000835.[28] The speakers confirmed that they spoke on-label at speaker events and, pursuant to policy, limited off-label discussion to individual responses to unsolicited questions based on their medical experience and without influence by Aventis. SUMF ¶ 91, Ex. 30A, 1996 Policies for Representative Conduct, SAVGOH-04100000758; Ex. 9, George Decl. ¶ 12; Ex. 8, Eisenberger Decl. ¶ 12; Ex. 11, Vogelzang Decl. ¶ 15.[29] Aventis also required speakers to acknowledge that their "payments constitute fair market value and have not been determined in a manner that takes into account the volume or value of any referrals generated between the parties." SUMF ¶ 93, Ex. 30A, 1996 Policies for Sales Representative Conduct, Sample Speaker Agreement, SAVGOH-04100000836.[30]

B. Advisory Boards.

Aventis held consultant-type advisory boards, where oncologists and hematologists met to discuss their clinical experiences with Taxotere, including its strengths and weaknesses. SUMF ¶ 95, Ex. 43, Corrigan 2018 Dep. 58. Advisory boards "allow[ed] oncologists to remain current on drug properties, benefits and side effects of drugs, and to review clinical trial results."

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[28] *See also* SUMF ¶ 90, Ex. 48, 1997 Speaker Agreement, SAVGOH-02800188296; Ex. 49, 1998 Speaker Agreement, SAVGOH-02800011544; Ex. 50, 1999 Speaker Agreement, SAVGOH-02800014818; Ex. 51, 2000 Speaker Agreement, SAVGOH-02800019611; Ex. 52, 2001 Speaker Agreement, SAVGOH-02800011544; Ex. 53, 2002 Speaker Agreement, SAVGOH-02800001614.

[29] Consistent with then-industry standard norms and a lack of guidance against such practices, Aventis provided meals, entertainment, and gifts to physicians in tandem with promotional and/or educational programming. However, its policies imposed restrictions on the type, amount, purpose, and frequency of these benefits. SUMF ¶ 92, Ex. 54, 1997 Business Ethics Policies, at SAVGOH-02800177603–06 (Policy #5); Ex. 30D, 2003 Policy & Procedure Manual, at SAVHGOH-02800174680–86 (Policy 502); Ex. 43, Corrigan 2018 Dep. at 86–87.

[30] *See also* SUMF ¶ 93, Ex.54, 1997 Business Ethics Policies, at SAVGOH-02800177580 (requiring that no agreement could be "entered into with implicit or explicit agreement to purchase, prescribe, recommend, influence, or provide favorable formulary status for RPRP products."). Aventis policy permitted fair-market compensation and reimbursement for reasonable expenses. SUMF ¶ 94, *Id.* at SAVGOH-02800177581.

SUMF ¶ 96, Ex. 19, Goldberg Report at 10.[31] Aventis compensated advisory board participants for their time at fair market value, consistent with industry standard, and Aventis's use of advisory boards accorded with those of other manufacturers nationwide. SUMF ¶ 97, *supra* n.34.

C. Preceptorships.

In a preceptorship, an Aventis sales representative visited an oncologist's practice for a day and gained firsthand experience and knowledge of how the physician treated her patients. SUMF ¶ 98, Ex. 43, Corrigan 2018 Dep. 28–30; 34; Ex. 10, Scholz Decl. ¶ 14. Physicians and sales representatives alike agreed that preceptorships were invaluable educational opportunities for Aventis personnel. SUMF ¶ 99, Ex. 35, Corrigan 2019 Dep. 139; Ex. 10, Scholz Decl. ¶ 14. Aventis policy mandated that preceptorships be strictly educational, rather than promotional events, and physicians received a small, industry-standard, and fair-market value stipend. SUMF ¶ 100, Ex.30D, 2003 Policy & Procedure Manual, at SAVGOH-02800174711 (Policy 509); *see also* Ex. 43, Corrigan 2018 Dep. 34:10–19; Ex. 10, Scholz Decl. ¶ 14. Policy also required that preceptorships could not involve off-label drug uses. SUMF ¶ 101, Ex. 30A, 1996 Policies for Representative Conduct, Sample Speaker Agreement, Preceptorships, SAVGOH-04100000764.

D. Educational Funding.

Finally, Aventis sponsored healthcare institutions that sought to enhance their clinical understanding of Taxotere in various disease states in two ways: educational programming and clinical trials. *See, e.g.*, SUMF ¶ 102, Ex. 30D, 2003 Policy & Procedure Manual, at SAVGOH-02800174695. First, Aventis awarded educational grants "to support bona fide educational programs for patients, consumers, and/or health care professionals." SUMF ¶ 103, *id*. In response

[31] *See also* SUMF ¶ 96, Ex. 6 Barker Decl. ¶ 10; Ex. 7, Dugan Decl. ¶ 17; Ex. 8, Eisenberher Decl. ¶ 15; Ex. 10, Scholz Decl. ¶ 12; Ex. 11, Vogelzang Decl. ¶ 16.

to healthcare providers' requests for sponsorship, Aventis funded physician education, including CME programs.[32] SUMF ¶ 104, Ex. 43, Corrigan 2018 Dep. 76; Ex. 55, Mount Sinai CME, at SAVGOH-03600000351 (showing that Aventis was one of sixteen pharmaceutical companies providing educational grants, and one of fifty-seven industry sponsors). Aventis did not control how grantees spent the allocated funds, Ex. 35, Corrigan 2019 Dep. at 286–87; Ex. 43, Corrigan 2018 Dep. at 70–71, 146, nor did it seek to influence or control the content or substance of these events. SUMF ¶ 105, Ex. 30A, 1996 Policies for Sales Representative Conduct, at SAVGOH-04100000829–833 (Sample Agreement for Educational and Scientific Activities); Ex. 4, Arnold Decl. ¶ 13.[33] Aventis policy stated that "under no circumstances may a grant be offered with the intent of … directly or indirectly … encouraging, inducing, or influencing…." SUMF ¶ 107, Ex. 30 D, 2003 Policy & Procedure Manual, SAVGOH-02800174697.

Similarly, Aventis, like other manufacturers, supported investigator-initiated studies proposed by oncologists who sought to investigate novel drug uses. SUMF ¶ 108, Ex.30D, 2003 Policy & Procedure Manual, at SAVGOH-02800174705 (Policy 506); Ex. 58, Chin (Senior Product Manager) Dep. 169–70; Ex. 59, Flannelly (Head of Marketing) Dep. 28. Aventis directed funding to the sponsoring institutions, and individual practitioners joined these clinical studies to support their own academic and clinical interests. SUMF ¶ 109, Ex. 8 Eisenberger Decl. ¶ 13. The researchers conducting the studies did so independently, with no intervention, input, or oversight from Aventis. SUMF ¶ 110, *id.* Likewise, Aventis played no role in selecting

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[32] *See* SUMF ¶ 104, Ex. 27, Bradshaw Report ¶ 96 ("[A] manufacturer may support CME programs if it does not influence the content of the activity and its financial support is disclosed.").

[33] To further ensure compliance with the relevant law and guidance pertaining to educational programming, Aventis contracted with third-party vendors Envision and Co-Med to coordinate the logistics and content of these programs directly with providers to further distance itself from the programming. *See* SUMF ¶ 106, Ex. 56, 1998 Envision Agreement, SAVGOH-02800028080; Ex. 57, 2002 Envision Agreement, SAVGOH-02800019444.

physicians to participate in the studies, who opted to participate of their own accord. SUMF ¶ 111, Ex. 19, Goldberg Report at 10–11. Support of these studies was and is the norm in the industry, was not conditioned on Taxotere prescriptions, and did not otherwise induce referrals. SUMF ¶ 112, Ex. 31, Naigamwalla Report ¶ 12; Ex. 8, Eisenberger Decl. ¶ 13; Ex. 10, Scholz Decl. ¶ 15. Nor did Aventis ever attempt to influence the results of the studies or publications associated with them. SUMF ¶ 113, Ex. 8, Eisenberger Decl. ¶ 13; Ex. 10, Scholz Decl. ¶ 15.

Aventis, like its industry peers, sponsored these studies to further scientific understanding of its drugs, for better or worse. SUMF ¶ 114, Ex.30D, 2003 Policy & Procedure Manual, at SAVGOH-02800174705 (Policy 506); Ex. 58, Chin Dep. 169–70; Ex. 59, Flannelly Dep. 28. At times, these research studies led to breakthrough discoveries that ultimately offered lifesaving and life-improving benefits to cancer patients. *See, e.g.*, SUMF ¶ 115, Ex. 16, TAX 326, at 15; Ex. 60, Ctr. for Drug Eval. & Research, Approval Package for Application No. 20-449/S-018, at 24. For example, the Aventis-sponsored TAX 326 study group found in part that a Taxotere-combination showed "significant improvement in overall survival and 2-year survival" compared with other chemotherapeutic regimens, thereby offering patients better tolerability and fewer debilitating side effects. SUMF ¶ 115, *id.*

Aventis lawfully used these programs to further legitimate commercial interests in on- and off-label uses of Taxotere, and implemented robust programs to ensure employee compliance. Gohil nevertheless alleges that Aventis engaged in a nationwide fraud scheme to induce unlawful prescriptions. He has, however, identified no evidence to raise a triable issue of fact. Summary judgment should therefore be granted in favor of Aventis.

LEGAL STANDARD

Summary judgment should be entered in favor of a movant that shows "no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). "Facts that could alter the outcome are 'material,'

and disputes are 'genuine' if evidence exists from which a rational person could conclude that the position of the person with the burden of proof on the disputed issue is correct." *Ideal Dairy Farms, Inc. v. John Labatt, Ltd.*, 90 F.3d 737, 743 (3d Cir. 1996). A court should grant summary judgment where "the non-moving party fails to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof." *Moody v. Atl. City Bd. Of Educ.*, 870 F.3d 206, 213 (3d Cir. 2017) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). "In such a situation, there can be 'no genuine issue as to any material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." *Celotex*, 477 U.S. at 317. Once the movant meets its burden, the opposing party "must point to actual evidence in the record on which a jury could decide an issue of fact its way." *El v. SEPTA*, 479 F.3d 232, 238 (3d Cir. 2007).

ARGUMENT

I. Gohil has Proffered Insufficient Evidence to Raise a Genuine Issue of Material Fact as to Whether Aventis Violated the False Claims Act.

After reviewing hundreds of thousands of documents and deposing dozens of witnesses, Gohil is no better situated to prove his meritless claims than when he initiated this lawsuit almost twenty years ago. Despite the voluminous record, Gohil has identified no evidence raising a genuine issue of material fact on any element of his FCA claim.

The FCA generally ensures requests for federal reimbursement are truthful, and penalizes those who submit false claims for payment. *Universal Health Servs., Inc. v. U.S. ex rel. Escobar*, 136 S. Ct. 1989, 1996 (2016). It is not, however, "an all-purpose antifraud statute … or a vehicle for punishing garden-variety … regulatory violations." *Id.* at 2003 (internal quotation marks and citation omitted). A defendant may be liable under the FCA only where it "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C.

§ 3729(a)(1)(A). A relator must prove (1) a false or fraudulent claim (2) material to the decision-making process, (3) which the defendant presented, or caused to be presented, to the United States for payment or approval, (4) knowing the claim was false or fraudulent. *E.g.*, *United States v. Celgene Corp.*, 226 F. Supp. 3d 1032, 1037 (C.D. Cal. 2016).

Gohil fails on each element. He has no evidence to show Aventis engaged in an extensive fraudulent scheme to promote Taxotere, or that any reimbursement claim for Taxotere was false due to Aventis's promotional or educational efforts. Because the Government repeatedly declined to intervene in Gohil's case and continued to reimburse Taxotere claims despite having detailed knowledge of Aventis's alleged misconduct, Gohil cannot prove that Aventis's common and industry-standard practices were material to the Government's reimbursement decisions. Likewise, Gohil lacks evidence of a single doctor writing a single prescription or making a single claim for Government reimbursement caused by Aventis's allegedly improper conduct. Finally, due to Aventis's robust compliance efforts and the lack of official guidance for the majority of the Relevant Period, Gohil cannot prove Aventis knowingly violated the law. Consequently, summary judgment should be entered in favor of Aventis.

A. Gohil Cannot Prove That Any Taxotere Claim Was False.

Claims to the Government may be "false" under the FCA in two ways: they may be (1) "factually false" where the "defendant misrepresents what goods or services that it provided to the Government;" or (2) "legally false" where the defendant "knowingly falsely certifies that it has complied with a statute or regulation the compliance with which is a condition for Government payment." *U.S. ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 305 (3d Cir. 2011). False certification of compliance with the AKS is one form of legal falsity. *U.S. ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 534 (S.D.N.Y. 2014).

Gohil advances faulty arguments under both theories as to why claims for federal reimbursement of Taxotere were "false." First, he alleges Aventis engaged in a "Fraudulent Marketing Scheme" to induce oncologists to prescribe Taxotere for clinical uses that were off-label or otherwise "not medically necessary" and therefore factually false. *E.g.*, TAC, ECF 134 ¶¶ 50, 57. Not only is there no evidence of record to support this wide-ranging allegation, Gohil also misapprehends modern oncology practice and improperly second-guesses oncologists' clinical decisions. Doctors in general, and oncologists in particular, routinely prescribe drugs for off-label use after determining those drugs are medically necessary given their patients' medical profiles and available treatment options. Second, Gohil alternatively seeks to prove "legal falsity" by alleging that Aventis violated the AKS by paying "kickbacks" to oncologists to induce Taxotere prescriptions, which caused the submission of reimbursement claims that falsely certified AKS compliance. Because Gohil has not, and cannot show that Aventis committed a predicate AKS violation, neither falsity theory survives summary judgment.

1. Gohil Cannot Prove Any Off-Label Prescriptions Were Factually False.

By asserting that reimbursement claims for off-label Taxotere were "false," Gohil improperly seeks to undermine the deference federal law affords oncologists and their clinical judgment. Neither the FDA nor CMS aims to control physicians' decision-making. Federal laws defer to physicians to make decisions in their patients' interests. 21 U.S.C. § 396. They particularly recognize the acute need for physician discretion in oncology, where treatment options are few and patients cannot wait for FDA approval for potentially life-saving drugs. Ex. 14, Cockburn Report ¶¶ 21–24; Ex. 61, Jena Report ¶¶ 23, 25. This need for informed but

innovative clinical judgment is why Congress authorized federal reimbursement of off-label uses of cancer drugs like Taxotere.[34]

Gohil also improperly second-guesses scientifically supported uses of Taxotere. As discussed above, oncologists and federal insurers had ample resources and reason to believe off-label Taxotere prescriptions were "reasonable and necessary" and therefore reimbursable. Clinical studies and thousands of journal articles informed doctors about Taxotere's therapeutic benefits and potential risks. *See supra* Facts § IV(A). These studies did not merely evaluate approved uses of Taxotere—nearly half examined Taxotere for unapproved indications. *See* Ex. 14, Cockburn Report ¶ 39 (noting that by 2004, around 43% of Taxotere studies examined off-label uses). These sources reflected the unique clinical benefits Taxotere offered, even where that particular use was not FDA-approved. *See supra* Facts § IV(A). *See also* Ex. 10, Scholz Decl. ¶¶ 8–9; Ex. 11, Vogelzang Decl. ¶¶ 8–11. With this wealth of research information at their disposal, oncologists had both the information and the authority to prescribe Taxotere for off-label use. Gohil is in no position to claim otherwise.

Because of these well-demonstrated clinical successes, and consistent with norms of oncology practice, physicians routinely prescribed Taxotere off-label. *See*, *e.g.*, Ex. 13, Unger, *supra*, at 4; Ex. 14, Cockburn Report ¶¶ 18–20; Ex. 10, Scholz Decl ¶. 8. They did so because Taxotere offered their patients the best chances of survival or improved quality of life. Ex. 10, Scholz Decl. ¶ 8; Ex. 11, Vogelzang Decl. ¶¶ 8–11. One physician even became known locally as the oncologist "whose patients do not die" because of his off-label uses of Taxotere. Ex. 7, Dugan Decl. ¶ 8. Taxotere's effectiveness was so profound and widely accepted that it became

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[34] *See* Ex. 62, Am. Cancer Soc'y, *Off-Label Drug Use*, https://www.cancer.org/treatment/treatments-and-side-effects/treatment-types/off-label-drug-use.html (limits for experimental or investigational drugs uses are "addressed through … federal legislation that requires insurance to cover medically appropriate cancer therapies"); *see also* Ex. 27, Bradshaw Report § II (FDA "lacks the authority to regulate the clinical practice of medicine").

the standard of care for some cancers, even before it received FDA approval for those indications. Ex. 11, Vogelzang Decl. ¶ 8. Indeed, it is the prescribing physician who is "best suited to evaluate each patient and determine whether a treatment is reasonable and necessary *for that individual patient.*" *Petratos v. Genentech Inc.*, 855 F.3d 481, 489 (3d Cir. 2017) (internal quotation marks omitted, brackets altered, emphasis in original). Here, the oncologists prescribing Taxotere off-label, and the federal insurers reviewing their reimbursement claims, had substantial research and the approval of the oncology community to support their determinations that off-label uses of Taxotere were reasonable and necessary for individual patients. And, in those instances where federal insurers did not believe a prescription for Taxotere was reasonable and necessary, reimbursement was denied.

Finally, Gohil has not shown federal insurers believed these claims were "false." There is no evidence that CMS rejected a single Taxotere claim on this basis or sought to recoup a penny paid for such claims.[35] Gohil cannot square this lack of evidence with his allegations of a far-reaching "fraudulent" campaign that rampantly induced false claims. Had CMS believed any claims for Taxotere were false, it would have investigated, ceased payment, and moved to recover the funds. Ex. 21, Romano Report ¶ 38. Thus, Gohil's argument lacks merit. He simply cannot show that oncologists treating patients, often in life-or-death situations, wrote medically unnecessary Taxotere prescriptions leading to false claims for federal reimbursement.

2. Gohil Cannot Show That Aventis Violated the AKS or That AKS Violations Resulted in False Claims to the Government.

In Count II of the TAC, Gohil seeks to establish FCA liability on a theory that Aventis violated the AKS. He claims that Aventis induced physicians to prescribe Taxotere by providing

[35] As evidenced by DDMAC's Untitled and Warning Letters, the FDA was well aware of Aventis's alleged marketing "misconduct" and had every opportunity to encourage CMS to reject payment, yet no such thing ever happened. *See supra* n.18.

them remuneration, and that when the physicians then sought federal reimbursement, they submitted claims that falsely certified compliance with the AKS. To succeed on this theory of legal falsity, Gohil must prove all of the elements of the predicate AKS violation by showing that Aventis: (1) willfully and knowingly (2) gave a thing of value/remuneration to a physician (3) to induce that physician to write prescriptions resulting in a false claim for payment to a federal healthcare program.[36] 42 U.S.C § 1320a-7b(b)(2). Gohil cannot prove a predicate AKS violation and thus cannot prove falsity for the purposes of his FCA claim on this theory.

a. There Is No Evidence That Aventis Willfully and Knowingly Engaged in Illegal Conduct.

The AKS's heightened "willfulness" standard requires a relator to prove that the defendant "knew his conduct was unlawful and intended to do something the law forbids." *United States v. Goldman*, 607 F. App'x 171, 174 (3d Cir. 2015). Gohil cannot do so.

1) Gohil Cannot Show That Any Aventis Employee Intended to Violate the Law.

To begin, Gohil cannot rely on a theory of "collective intent" to prove Aventis acted with the requisite scienter. Instead, he must show that at least one Aventis corporate official or manager, rather than a mere employee, "knowingly and willfully" acted to induce unlawful prescriptions. *In re Tyson Foods, Inc. Sec. Litig.*, 155 F. App'x 53, 57 (3d Cir. 2005) (citing *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 366 (5th Cir. 2004) (rejecting

[36] Along with proving the underlying AKS violation, the FCA falsity element requires a relator to proffer evidence of the submission of at least one false claim premised on a "kickback" to prevail on summary judgment. As the Third Circuit has instructed, "[a] kickback does not morph into a false claim unless a particular patient is exposed to an illegal recommendation or referral and a provider submits a claim for reimbursement pertaining to that patient…. [W]e must have some record evidence that shows a link between the alleged kickbacks and the medical care received by at least one … federally insured patient[ ]." *U.S. ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89, 100 (3d Cir. 2018).

the notion that "the collective knowledge of all the corporation's officers and employees acquired in the course of their employment" could satisfy scienter)).[37]

Gohil has presented no evidence that any member of Aventis's management intended to violate the law. To the contrary, repeated and undisputed deposition testimony from Aventis's then-management confirms that Aventis always sought to comply with the law.[38] And, as detailed below, Aventis's compliance program ensured Aventis personnel complied with the law, and punished employees who violated company policy. *See Supra* Facts § IV(B). Accordingly, Gohil's AKS argument fails because he cannot prove scienter.

2) Aventis Sought to Comply with the AKS, Even in the Absence of Official Guidance.

The evidence reflects that Aventis sought to comply with applicable laws, and that its promotional or educational programs did not violate the AKS. For most of the Relevant Period, there were no regulations or guidance to assist Aventis (or its industry peers) in collaborating with physicians while avoiding AKS liability. *See supra* Facts § IV(A). Aventis, though, sought in good faith to establish a culture of AKS compliance, voluntarily implemented policies related to its promotional and educational efforts as early as 1996, and trained its employees on the scope and consequences of the AKS.[39] These policies applied to and restricted all promotional and educational programs at issue. *See supra* Facts § IV(A). Such robust programs gave Aventis

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[37] *See also Chaney v. Dreyfus Serv. Corp.*, 595 F.3d 219, 241 (5th Cir. 2010) (internal citations omitted) (declining to allow scienter to be met by a corporation's collective knowledge and "instead requiring that the state of mind 'actually exist' in at least one individual"); *United States v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010) ("We know of no circuit that has applied the 'collective knowledge theory' to the FCA.").

[38] *E.g.*, Ex. 35, Corrigan 2019 Dep. 294:22–295:9 ("I think it really—it was endemic within the entire organization that compliance was everybody's responsibility; everybody's responsibility to report, everybody's responsibility to be in alignment with and ultimately, you know, liable for."). *See also* Ex. 47, Fleming Dep. 302:17–303.

[39] See Ex. 30A, 1996 Policies for Sales Representative Conduct, at SAVGOH-04100000754–837.

no reason to believe that its practices violated the AKS, and, in fact they did not.[40] And Aventis's promotional and educational programs remained lawful even after the 2002 PhRMA Code and 2003 OIG Guidance were released. Aventis's pre-2002 policies largely anticipated and mirrored the recommendations set forth in the official guidance. *See* Ex. 30, Demonstrative Exhibit Comparing Compliance Policies. In the few, minor instances in which its earlier policies fell short of these new and stringent guidelines, Aventis modified its policies accordingly. *See* Ex. 30, Demonstrative Exhibit Comparing Compliance Policies; Ex. 29, Baylor-Henry Report ¶ 77 ("Sanofi … adopted and embraced the PhRMA Code.").

In sum, Aventis lacked reason to believe its conduct was unlawful. It collaborated with physicians through sponsored programs at a time when the Government offered no regulations or guidance to suggest such relationships were unlawful. Even so, Aventis implemented robust compliance activities to ensure that its legitimate promotional and educational programs did not lead to payment of improper kickbacks. These efforts reflect Aventis's forward-thinking desire to comply with applicable laws and guidance, and preclude any argument that Aventis "intended to do something the law forbids." *Goldman*, 607 F. App'x at 174.

b. Aventis's Physician and Research Funding Programs Do Not Constitute Illegal Remuneration.

Aventis's payments to physicians during the Relevant Period served legitimate and legal purposes and were not illegal remuneration.[41] As detailed above, Aventis's support of events constituted lawful promotion of Taxotere and efforts to educate the medical community and develop medical breakthroughs. The 2002 PhRMA Code and 2003 OIG Guidance recognize that

[40] Indeed, these extensive policies largely anticipated and mirrored the 2002 PhRMA Code and the 2003 OIG Guidance. *See* Ex. 30, Demonstrative Exhibit Comparing Compliance Policies, at 30B and 30C.

[41] For the purposes of the AKS, remuneration is defined broadly as any "thing of value." *Klaczak v. Consolidated Med. Transp.*, 458 F. Supp. 2d 622, 678 (N.D. Ill. 2006).

pharmaceutical funding for activities such as medical education and clinical studies is beneficial to both the industry and community. Ex. 30B, 2002 PhRMA Code § 1; Ex. 30C, 2003 OIG Guidance at 23,738. Thus, rather than ban physician-pharma collaborations, PhRMA and the OIG sought to distinguish useful and proper interactions from those that risk AKS consequences.

As outlined above, Aventis's various promotional and educational programs were lawful because they conformed to available guidance and industry norms. Aventis ensured these programs served educational and scientific ends, compensated participants at fair market value, reimbursed physicians for appropriate costs, and did not condition payment on Taxotere prescriptions. *See supra* Facts § V. Aventis maintained robust policies ensuring AKS compliance, updated its policies when necessary, trained employees, and intervened if employees violated the policies. Aventis's payments to oncologists in conducting these programs were legal and legitimate.[42] Further, Aventis's use of third-party vendors to administer these lawful programs does not alter this conclusion or reflect an effort to conceal improper payments to doctors. Indeed, the record reflects that the vendors also complied with laws and industry standards, doctors received fair market value for their participation in these programs, and funds were never contingent on prescribing Taxotere.[43] *See, e.g.*, *Celgene*, 226 F. Supp. 3d at 1053

[42] *See, e.g., U.S. ex rel. King v. Solvay Pharm., Inc.*, 871 F.3d 318, 332 (5th Cir. 2017) (affirming summary judgment for defendant because "[t]here was nothing illegal about paying physicians for their participation in [consultation and presentation] programs and there is no evidence that participation was conditioned upon prescribing [defendant's] drugs to Medicaid patients").

[43] Ex. 4, Arnold Decl. ¶ 15; Ex. 6, Barker Decl. ¶ 10; Ex. 7, Dugan Decl. ¶¶ 14–17; Ex. 8, Eisenberger Decl. ¶¶ 12, 15–16; Ex. 9, George Decl. ¶¶ 12–14; Ex. 10, Scholz Decl. ¶¶ 12–15; Ex. 11, Vogelzang Decl. ¶¶ 14–17; *see also* Ex. 48, 1997 Speaker Agreement, SAVGOH-02800188296; Ex.49, 1998 Speaker Agreement, SAVGOH-02800011544; Ex. 50, 1999 Speaker Agreement, SAVGOH-02800014818; Ex. 51, 2000 Speaker Agreement, SAVGOH-02800019611; Ex. 52, 2001 Speaker Agreement, SAVGOH-02800011544; Ex. 53, 2002 Speaker Agreement, SAVGOH-02800001614.

(granting summary judgment for drug manufacturer; finding no intent to induce where programs were organized by vendor, speakers were paid flat fee, and other companies paid comparably).[44]

Because Aventis's promotional and educational programs comported with laws, guidance, and industry norms, none of the payments that physicians received through these programs constituted illegal remuneration. Gohil has no evidence to the contrary.

c. Aventis Did Not Intend Payments Made in Connection with Its Promotional or Educational Programs to Induce Unlawful Prescriptions.

Gohil cannot satisfy the AKS's "inducement" element with evidence that Aventis "merely hoped" its conduct would unlawfully induce Taxotere prescriptions. *U.S. ex rel. Ruscher v. Omnicare, Inc.*, 633 F. App'x 368, 374–75 (5th Cir. 2016) (citing *United States v. McClatchey*, 217 F.3d 823, 834 (10th Cir. 2000)). Instead, he must offer evidence to prove that at least "one purpose" of Aventis's conduct was to induce oncologists to write Taxotere prescriptions. *United States v. Greber*, 760 F.2d 68, 69 (3d Cir. 1985).

As discussed above, Aventis used its programs for educational and scientific purposes. Each policy pertaining to a promotional or educational program specifies Aventis's purpose for that program, and implemented structural safeguards to ensure each partnership furthered that purpose.[45] Ex. 30, Demonstrative Exhibit Comparing Compliance Policies. *See also* Ex. 31, Naigamwalla Report ¶ 116 ("[R]esearch …, training, … and plans for commercialization do not suggest wrongdoing of any kind."). Likewise, by providing grants to support clinical trials,

[44] Indeed, Aventis's use of third-party vendors to administer some of these programs consistent with the law and company policies further evidences Aventis's good-faith attempts to ensure the propriety of such programs. *See United States v. Pfizer, Inc.*, 188 F. Supp. 3d 122, 134 (D. Mass. 2016) (granting summary judgment that speaker series was not, as alleged, a "sham" designed to conceal kickbacks or violate the FCA, noting the use of "external consultants to establish fair market value for its speaker series, provide[ ] trainings to comply with anti-kickback requirements, and otherwise establish[ ] systems that purportedly protect against the speaker series turning into a kickback scheme"), *aff'd sub nom. U.S. ex rel. Booker v. Pfizer, Inc.*, 847 F.3d 52 (1st Cir. 2017).

[45] Ex. 30A, 1996 Policies for Sales Representative Conduct, at SAVGOH-04100000754–837.

Aventis sought only to advance scientific knowledge and expedite the development of potentially life-saving cancer treatments.[46] *See supra* Facts § V(D) (explaining compliance of Aventis's research programs). Oncologists who participated in these programs and received payments confirm their participation was unrelated to their Taxotere use, and that they did not believe Aventis sought to improperly influence their clinical judgment by asking them to participate or paying honoraria. Aventis's purposes for its promotional and/or educational programs, its legal compliance (including that all payments to physicians were at fair market value), and oncologist statements all confirm that Aventis did not seek to induce Taxotere prescriptions with these programs. Gohil's inability to prove otherwise warrants summary judgment.

B. Gohil Has Failed to Show Any Claim Was Material to the Government's Payment Decision.

Aventis's legal, common, and industry-standard practices were not material to the Government's decision to reimburse for claims Taxotere. The Government's repeated refusal to intervene in Gohil's case, and continued reimbursement of Taxotere claims—despite its extensive actual knowledge of Aventis's conduct—confirms this lack of materiality. *Escobar*, 136 S. Ct. at 1996. Because there is no evidence to prove or suggest otherwise, Gohil also cannot establish materiality, as well.

The Supreme Court in *Escobar* reaffirmed that materiality is a "demanding" and "rigorous" standard intended to prevent relators from transforming the FCA into "an all-purpose anti-fraud statute … or a vehicle for punishing garden-variety … regulatory violations." *Id*. at

[46] At all times, the Government has recognized that pharmaceutical companies fund research programs to further legitimate and important medical and scientific ends. *See, e.g.*, Publication of OIG Special Fraud Alerts, 59 Fed. Reg. 65372-01 (Dec. 19, 1994) (noting that pharma-sponsored research "offer[s] substantial benefits" to the medical community); Ex. 30C, OIG 2003 Guidance, at 23,736 ("In many cases, the research provides valuable scientific, and clinical information, improves clinical care, leads to promising new treatments, promotes better delivery of healthcare, or otherwise benefits patients.").

1996, 2003 (internal quotation marks and citation omitted). Gohil can establish materiality only if he can point to a misrepresentation to which the government "would attach importance … in determining" whether to reimburse for Taxotere, and if such knowledge "would have induced [the government] to act differently." *Id.* at 2002–03 & n.5 (internal quotation mark omitted); *accord* 31 U.S.C. § 3729(b)(4). A defendant's conduct is immaterial where it is minor or insubstantial in nature. *Id*.

Two scenarios are probative of immateriality: where: (1) the Government had "actual knowledge" of a defendant's alleged wrongdoing but continued to pay claims, *Escobar*, 136 S. Ct. at 2003–04;[47] and (2) the Government refuses to intervene in a case after investigating a relator's claims. *Petratos*, 855 F.3d at 490.[48] Both are present here. First, the Government gained "actual knowledge" of Aventis's alleged conduct after Gohil filed his initial complaint in 2002. The Government's actual knowledge cannot reasonably be disputed, given that Gohil provided the Government fourteen sets of formal disclosures about Aventis's marketing and sales practices, including of hundreds of pages of correspondence with the Government, hours of recorded audio, and tens of thousands of pages of documents. *See generally* Ex. 2, Compilation of Relator's Disclosures to Gov't. The Department of Justice ("DOJ") and DHHS investigated Gohil's allegations for at least four years, yet the Government never intervened in this case. It

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[47] Information obtained by government agencies is imputed to "the Government" in a materiality analysis. *U.S. ex rel. Ubl v. IIF Data Sols.*, 650 F.3d 445, 453 (4th Cir. 2011) ("We see no reason why the government's knowledge would become irrelevant simply because the employees with the knowledge do not work for the particular agency that happens to pay the contractor's invoices."); *U.S. ex rel. McBride v. Halliburton Co.*, 848 F.3d 1027 (D.C. Cir. 2017) (granting summary judgment for defendants on materiality after agency investigated relator's claims, noting that "neither [the agency] nor *any other Government agency* disallowed or challenged any of the amounts"); *United States v. Sanford-Brown, Ltd.*, 840 F.3d 445, 447 (7th Cir. 2016) (upholding grant of motion to seal and return based on materiality element because "subsidizing agency and other federal agencies in this case 'have already examined [program] multiple times over and concluded that neither administrative penalties nor termination was warranted.'").

[48] *See also McBride*, 848 F.3d at 1033 (affirming summary judgment in FCA matter based in part on government testimony that allegedly false information provided by a contractor "had no bearing on costs billed to the Government," establishing immateriality based on the Government's continued payment despite actual knowledge).

first declined in 2006, and did so later in 2007 and 2015 in response to Gohil's amended complaints.[49] *See, e.g.*, ECF No. 24.

Second, it is undisputed that throughout the Relevant Period and thereafter, the Government continued to approve payments for Taxotere without interruption. *See U.S. ex rel. Janssen v. Lawrence Mem'l Hosp.*, 949 F.3d 533, 542 (10th Cir. 2020) (granting summary judgment on materiality: CMS's "inaction in the face of detailed allegations from a former employee [of defendant] suggests immateriality"); *see also* Ex. 61, Jena Report ¶ 74, at Ex. 1 (detailing Medicare paying for Taxotere without interruption during Relevant Period).[50] Ex. 30, Demonstrative Exhibit Comparing Compliance Policies. Thus, despite having investigated Relator's claims for years and amassing extensive information about Aventis's alleged misconduct, the Government neither intervened nor halted payment of Taxotere claims. This is "very strong" evidence that Aventis's conduct was immaterial. *Escobar*, 136 S. Ct. at 2003–04.[51] Nothing Gohil can point to rebuts such a finding or otherwise satisfies *Escobar*'s stringent materiality standard.

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[49] Not only did the Government conduct its own investigation, it coordinated with Relator to obtain Aventis's documents through Gohil's parallel employment action. Ex. 2B, Compilation of Relator's Disclosures to Gov't at GOH/COD000241–42 (email from Relator's counsel planning to interview physicians under pretense of unrelated litigation, inquiring what "degree of proof" the Government needed to proceed against Aventis so as not to "squander the opportunity to speak to these physicians" who did "not suspect anything other than the employment matter," and arranging to send Government recordings and transcripts of the interviews, to which the Government responded "Great. Good idea not to raise any red flags, . . . Great job!").

[50] Indeed, after Gohil's 2002 report to the Government of Aventis's alleged "wrongdoing," Taxotere was indicated for 6 new uses, further confirming that the Government's knowledge of Aventis's conduct was not so material as to hinder future FDA approvals. Ex. 3, Demonstrative Exhibit Detailing Taxotere's FDA-Approved Indications; *compare* Ex. 2B, Compilation of Relator's Disclosures to Gov't at GOH/COD000264 (Feb. 2004 email from Relator's counsel advising Government of Aventis's application for Taxotere indication in the adjuvant setting); *with* Ex. 3F, New Indication Approval Letter from FDA (Aug. 18, 2004) (approving Taxotere for adjuvant use).

[51] *Sanford-Brown*, 840 F.3d at 447 (7th Cir. 2016) (affirming summary judgment on materiality because "as we previously noted, the subsidizing agency and other federal agencies in this case 'have already examined [defendant] multiple times over and concluded that neither administrative penalties nor termination was warranted.'").

C. Gohil Cannot Show That Aventis Acted with the Requisite Scienter.

As detailed above with respect to the AKS's scienter requirement, Gohil cannot show that Aventis acted with the requisite state of mind under the FCA.[52] To establish scienter under the FCA, a relator must prove that the defendant knowingly violated the law, such that it acted with "actual knowledge of the information," "in deliberate ignorance of the truth or falsity of the information," or "in reckless disregard of the truth or falsity of the information." *U.S. ex rel. Spay v. CVS Caremark Corp.*, 875 F.3d 746, 758 (3d Cir. 2017) (citing FCA). Here too, a relator cannot rely on a theory of collective intent, but must prove that at least one employee knowingly violated the law. *E.g.*, *In re Tyson Foods, Inc. Sec. Litig.*, 155 F. App'x 53, 57 (3d Cir. 2005).[53]

Again, there is no evidence of an official or unofficial "scheme" to promote Taxotere improperly. Neither the documents, nor the testimony corroborate Gohil's claims that Aventis sales personnel marketed Taxotere off-label or misled oncologists into prescribing Taxotere.[54] Nor is there evidence that Aventis overstated Taxotere's efficacy or sought to deceive the FDA with respect to its promotional activities. Ex. 29, Baylor-Henry Report ¶ 91, 97, 101, 106; Ex. 27, Bradshaw Report at 37–50. Instead, sworn employee testimony and Aventis's rigorous off-label promotion policies and compliance infrastructure demonstrate Aventis's efforts to comply with applicable law. Ex. 29, Baylor-Henry Report ¶ 77–78; *see also supra* Facts § IV(B), (C)

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[52] As outlined above, both the FCA and AKS separately require showings of scienter, which Gohil must independently make to succeed on his claims.

[53] *Accord Chaney*, 595 F.3d at 241 (finding no scienter in company's collective knowledge and requiring requisite state of mind "actually exist" in at least one employee); *United States v. Sci Applications Int'l Corp.*, 626 F.3d 1257, 1274 (D.C. Cir. 2010) ("We know of no circuit that has applied the 'collective knowledge theory' to the FCA.").

[54] *See* Ex. 47, Fleming Dep. 310:23–313:2 (describing consistently providing instruction to area managers and sales representatives to "stay focused on the core messaging within our approved indication" and to refer any physicians making unsolicited requests for off-label information to Medical Affairs); Ex. 43, Corrigan 2018 Dep. 358:11–359:1 (explaining that he did not encourage off-label promotion and in fact underscored to sales representatives that the key to success was to stay focused on labeled indications which comprised the greatest volume of business).

(explaining Aventis's promotional compliance policies). Given this testimony and Aventis's efforts to prevent off-label promotion, Gohil is unable to show that Aventis knowingly or recklessly violated the FCA.

D. Gohil Cannot Show That Aventis's Promotional or Educational Programs Caused Oncologists to Submit False Claims.

Finally, Gohil cannot satisfy the causation element because he cannot identify a single doctor who wrote a single Taxotere prescription that resulted in a single claim for reimbursement because of Aventis's allegedly unlawful marketing and educational efforts. To the contrary, oncologists practicing during the Relevant Period testified that they prescribed Taxotere solely because of its clinical benefits and their own clinical judgement, despite any interaction they had with Aventis sales representatives.

To prove causation, Gohil must show that Aventis's allegedly unlawful marketing and kickback schemes were "substantial factors" in causing doctors to pass on claims for payment to Government payors. *E.g.*, *U.S. ex rel. Brown v. Celgene Corp.*, No. CV 10-3165-GHK SSX, 2014 WL 3605896, at *8 (C.D. Cal. July 10, 2014) (citing *U.S. ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3d Cir. 2004), for proposition that "[c]ourts borrow general tort law principles to analyze the FCA's causation element"); *Petratos*, 855 F.3d at 491 (noting that proof of "but for" causation is insufficient in FCA cases).

To survive summary judgment, Gohil must do more than baldly claim that alleged off-label promotion "must have" caused false claims to be submitted to the Government. *U.S. ex rel. Quinn v. Omnicare, Inc.*, 382 F.3d 432, 440 (3d Cir. 2004); *accord U.S. ex rel. Aflatooni v. Kitsap Physicians Servs.*, 314 F.3d 995, 1002 (9th Cir. 2002). Instead, he must prove that (1) Aventis's promotional activities caused doctors to write unlawful prescriptions, and (2) those prescriptions were subsequently presented to federal payors for reimbursement. *E.g.*, *Celgene*

Corp., 226 F. Supp. 3d at 1037. Gohil has done neither and there is no record evidence which supports such an allegation.

As for his "Fraudulent Marketing Scheme" allegations, Gohil claims Aventis induced oncologists to prescribe Taxotere off-label, and that oncologists in fact wrote off-label prescriptions. But even if both allegations were true, merely showing off-label promotion and off-label prescriptions *does not* prove—or even permit the inference—that the promotions *caused* the prescriptions.[55] Gohil cannot bridge this gap because no record evidence shows that Aventis's marketing practices *actually caused* oncologists to prescribe Taxotere off-label. *See Quinn*, 382 F.3d at 440. To the contrary, the only evidence on this point comes directly from the very oncologists who prescribed Taxotere, submitted claims for reimbursement, and were lawfully paid reimbursement by Medicare. Prestigious oncologists nationwide who collectively wrote more than 600 publications and treated thousands of cancer patients swore that:

> Any and all of the Taxotere prescriptions I have written were based on my medical judgment as an oncologist. At all times, I prescribed Taxotere because it was in the best interests of my patient given my experience, the patient's medical history and condition, the availability of treatment options, and the clinical data and medical literature concerning Taxotere, including Taxotere's safety and efficacy profile….[56]

These declarations, standing alone, shift the burden to Gohil to "designate specific facts demonstrating the existence of genuine issues for trial." *Celgene*, 226 F. Supp. 3d at 1037 (quoting *In re Oracle Corp. Sec. Litig.*, 627 F.3d 376, 387 (9th Cir. 2010)). Gohil cannot offer evidence sufficient to contradict this testimony or show that off-label marketing, and not science and sound medical judgment, caused physicians to prescribe Taxotere. Likewise, Gohil can show

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[55] Empirical evidence counsels against such an inference. Studies have shown that physicians rarely rely on information provided by pharmaceutical sales representatives when considering whether to prescribe off-label, Ex. 14, Cockburn Report ¶ 29, and that in-person communications with physicians may actually deter physicians from prescribing a particular company's drugs. Ex. 14, Cockburn Report ¶¶ 85–86.

[56] Ex. 4, Arnold Decl. ¶ 12; Ex. 6, Barker Decl. ¶ 9; Ex. 7, Dugan Decl. ¶ 14; Ex. 8, Eisenberger Decl. ¶ 5, 11; Ex. 9, George Decl. ¶ 11; Ex. 10, Scholz Decl. ¶ 11; Ex. 11, Vogelzang Decl. ¶ 3, 12; *see* Ex. 5, Austin Decl. ¶ 3, 9.

no direct causal link between an alleged AKS violation and the submission of any single Taxotere claim. *Greenfield*, 880 F.3d at 98–100 ("Greenfield must show . . . that at least one of the 24 federally insured patients for whom Accredo provided services and submitted reimbursement claims was exposed to a referral or recommendation … in violation of the [AKS]."). Gohil cannot prove that honoraria, research funding, or other lawful benefits caused any oncologist to write any unlawful prescription.[57] *See Solvay Pharm., Inc.*, 871 F.3d at 332 (granting summary judgment for failure to prove AKS violation because "it would be speculation to infer that compensation for professional services legally rendered actually caused the physicians to prescribe [defendant's] drugs").

The same physicians alleged here to have written false claims consistently denied any improper influence, and explained they relied exclusively on their own clinical judgment when prescribing Taxotere. Indeed, these oncologists have provided sworn statements that Aventis's promotional and/or educational programs, honoraria, and reimbursement payments, and funding of research and educational programs "were not contingent on the volume of Taxotere that I prescribed, nor did they affect, influence, or induce my prescription of Taxotere."[58] [59] Because Relator cannot contradict these sworn statements or otherwise establish a causal connection

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[57] Gohil himself stated that he was unaware of any physicians who prescribed Taxotere only because they participated in Aventis's programs. Gohil Dep. 81–82 (speaker programs); 358:1–7; 351:23–352:6 (preceptorships).

[58] Ex. 4, Arnold Decl. ¶ 15; Ex. 6, Barker Decl. ¶ 10; Ex. 7, Dugan Decl. ¶¶ 14–17; Ex. 8, Eisenberger Decl. ¶¶ 12, 15–16; Ex. 9, George Decl. ¶¶ 12–14; Ex. 10, Scholz Decl. ¶¶ 12–15; Ex. 11, Vogelzang Decl. ¶¶ 14–17.

[59] Detailed analysis of Taxotere prescriptions corroborates this point. Indeed, nearly 70% of the oncologists identified by Relator as having received alleged things of value from Aventis had already prescribed Taxotere to five or more patients *before* receiving anything of value. Ex. 14, Cockburn Report ¶ 54. Coupled with the evidence discussed above establishing that physicians are likely repeat-prescribe, and that few physicians wrote the vast majority of Taxotere prescriptions, this statistic suggests that a substantial amount of Taxotere prescriptions resulted from pre-thing of value decisions to prescribe Taxotere.

between Aventis's alleged kickbacks and any false claim, summary judgment is warranted for this final reason, as well.[60]

CONCLUSION

For all these reasons, Aventis's Motion for Summary Judgment should be granted.

Respectfully submitted,

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60 Relator's purely theoretical expert reports seeking to establish a causal relationship between Aventis's marketing activity and prescription decisions are flawed for three main reasons. *See generally* Ex. 14, Cockburn Report § IV. First, and most importantly, these experts fail to establish a causal—rather than correlative—relationship between things of value and physician prescriptions, or to disprove reverse causal or simultaneous causal relationships. *Id.* § IV.A. Second, they fail to properly account for the numerous factors (discussed above) that inform a physician's decision to prescribe off-label, and that confound the experts' attempts to establish a causal relationship. Finally, the experts rely on literature that does not account for the unique nuances of off-label oncology prescription, and use the literature to infer a causal connection when this literature expressly cautions against such an inference. *Id.* § IV.B. Indeed, these experts fail to consider statistical evidence most germane to this case, which concluded that industry payments did not influence prescription rates of cancer drugs. *Id.* ¶ 85. Furthermore, Relator's reliance on the testimony of expert Meredith B. Rosenthal, Ph.D. is similarly unsubstantiated. In reaching her conclusions, Rosenthal improperly and uncritically relied on the unsupported representations *of Relator's counsel. See, e.g.*, Ex.63 Rosenthal Report ¶ 10 (acknowledging herself that "[Relator's] [c]ounsel ha[d] informed [her] that these kickbacks are illegal"); Ex. 61, Jena Report ¶ 86 (detailing Rosenthal's reliance on instructions from Relator's counsel as her sole "methodology").